

## REMARKS

By the present amendment, applicants have amended the independent claims, Claim 29 and Claim 35, to include a melting point for Form X of 230 °C to 237 °C, and to specify that the degree of error is  $\pm$  0.2 degrees 2-Theta in Claim 29. Support for the melting point is found in applicants specification in Fig. 32 and on page 36, 3<sup>rd</sup> paragraph, wherein applicants state that Fig. 32 is a DSC thermogram of a sample isolated in the process described in Example 44 which describes Form X. Support for the degrees 2-Theta is found in Claim 35.

The Examiner has rejected Claims 29, 31, 33-37 and 41-43 under 35 U.S.C. 102(e) as being anticipated by Reddy et al. (US 2004/0097568 A1).

According to 35 U.S.C. §102(e), the Reddy et al. (US 2004/0097568 A1) patent application may not be used as a reference until the U.S. filing date of July 29, 2003. It is noted that applicants filing dates for losartan in crystal Form X under 35 U.S.C. §119 are Jan. 30, 2003, June 12, 2003, and June 26, 2003, all of which are prior to the 102(e) date of Reddy et al. (July 29, 2003). Thus, Reddy cannot be used as a reference against applicants claims relating to Form X.

In addition, a comparison of the 2-Theta values for applicants' potassium salt of losartan in crystal Form X, as claimed by applicants, and Reddy's potassium salt of losartan are summarized in Table I.

Table I

Applicants Form X	6.9	13.8	19.1	20.6	21.4	24.0	24.8	25.9	28.7	29.2
Reddy Form III	7.2	13.9	19.3	20.7	21.6	24.1	24.9	26.1	28.9	29.5

The data in Table I clearly shows that 6 out of the 10 values are at least 0.2 degrees 2-Theta different between applicants' Form X and Reddy's Form III. In addition, Reddy's Form III has a melting point of 254 °C to 260 °C, as stated on page 4, lines 18-20 of Reddy. In contrast, applicants' Form X has a melting point of 230 °C to 237 °C, as claimed by applicants. Thus, the melting point of applicants' Form X is at least 10% less than the melting point of Reddy's Form III. Therefore, Reddy's Form III does not anticipate applicants' Form X, as claimed.

The Examiner has rejected Claims 29, 31, 33-37 and 41-43 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

First, the Examiner states that Claims 29, 31 and 35 claims a potassium salt of losartan on crystal form X characterized by 7 peaks in a powder X-ray diffraction pattern, and the data provided in these claims is not sufficient to distinguish the claimed polymorph form the existing polymorphs.

In response, applicants have amended independent Claims 29 and 35 to include three additional peaks as determined in Fig. 31 of applicants' specification as follows: 19.1, 21.4, and  $25.9 \pm 0.2$  degrees 2-Theta.

Secondly, the Examiner states that an additional limitation such as the melting point of the claimed polymorph should be inserted into the claims in order to properly distinguish this claimed product over the prior art.

In response, applicants have amended the independent claims, Claim 29 and Claim 35, to include a melting point of 230 °C to 237 °C. Support is found in applicants specification in Fig. 32 and on page 36, 3<sup>rd</sup> paragraph, wherein applicants state that Fig. 32 is a DSC thermogram of a sample isolated in the process described in Example 44 which describes Form X.

In view of the above amendments and arguments, it should be unambiguously clear that Reddy does not teach or suggest applicants' potassium salt of losartan in crystal Form X, as claimed.

Respectfully submitted,

Novartis,  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080  
(609) 627-8507

  
John D. Thallemer  
Attorney for Applicants  
Reg. No. 34,940

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